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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,818	KREUTZ, WERNER	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 54-58 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 54-58 is/are rejected.

7)☒ Claim(s) 54-58 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/446,570.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 17 November 2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 54-58 are presented for examination.

Acknowledgment is made of the present application as a divisional application of U.S. Patent Application No. 10/371,088, filed February 21, 2003, now U.S. Patent No. 6,727,235, which is a divisional application of U.S. Patent Application No. 09/713,449, filed November 15, 2000, now U.S. Patent No. 6,525,038, which is a continuation-in-part (CIP) application of U.S. Patent Application No. 09/446,570, filed March 27, 2000, now U.S. Patent No. 6,395,720. Acknowledgment is also made of Applicant's claim for priority under 35 U.S.C. 119(a-d) to German Patent Application No. 19726871.4, filed June 24, 1997. Applicant's preliminary amendment filed November 17, 2003 has also been received and entered into the application. Accordingly, claims 1-53 have been cancelled and claims 54-58 are newly added. Applicant's Information Disclosure Statement (IDS) also filed November 17, 2003 has also been received and entered into the application. As reflected by the attached, completed copy of form PTO-A820 (one page total), the Examiner has considered the cited references.

Applicant's Claim for Priority under 35 U.S.C. 119(a-d) and 120

Applicant's claim for the benefit of a domestic-filed application (U.S. Patent Application Nos. 10/371,088; 09/713,449; and 09/446,570) under 35 U.S.C. 120 and Applicant's claim for the benefit of a foreign-filed application (German Patent Application No. 19726871.4) under 35 U.S.C. 119(a-d) is acknowledged. Applicant is reminded that the later-filed application must be an application for patent for an invention that has been disclosed in the prior application(s) (i.e., either the domestic or foreign-filed application). The disclosure of the invention in the earlier

application(s) and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Receipt is acknowledged of a certified copy of German Patent Application No. 19726871.4, filed June 24, 1997, which was submitted during the prosecution of parent U.S. Patent Application No. 09/466,570.

It has been determined that U.S. Patent Application No. 09/713,449, filed November 15, 2000, contains sufficient support and enablement as required under 35 U.S.C. 112, first paragraph, for the presently claimed subject matter drawn to a synergistic composition comprising 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid. This conclusion has been made with reliance on the results demonstrated in Figure 4 to show that the effect resulting from the combination of both agents was significantly greater than the effect shown for each individual agent alone. In light of this fact, the effective filing date of present claims 54-58 has been determined to be November 15, 2000.

The claims have not been granted the effective filing date of U.S. Patent Application No.09/466,570, filed March 27, 2000, or German Patent Application No. 19726871.4, filed June 24, 1997, because the specification(s) of such applications lack sufficient specificity for demonstrating the synergistic effect of the particular combination of 5-(2,4-difluorophenyl)salicylic acid when combined with 2,4,6-trihydroxybenzoic acid for the treatment of cancer.

Objections to the Claims

Claims 54-58 are objected to for failing to begin with an article. Claims 54-55 should be amended to read on "A synergistic composition..." as in claim 54 and "A medicament..." as in claim 55. Claim 56 should be amended to read on "A method of treating cancer..." and claims 57-58 that are dependent therefrom should be amended to read on "The method of treating cancer...".

Objection to the Specification

Applicant's preliminary amendment amending the present specification at page 1, paragraph 1, has been noted in the papers filed November 17, 2003. However, Applicant's reference to U.S. Patent Application No. 09/413,449 in the priority claim is in error. It appears that Applicant intends to claim priority to U.S. Patent Application No. 09/713,449, filed November 15, 2000. It is also noted that Applicant has not provided the current status of each of the applications to which it claims priority. Applicant is requested to amend the cross-reference to these related applications to properly reflect the serial number and current status of the application.

Applicant may wish to consider amending page 1, paragraph 1, in the following manner. Applicant is reminded that the following is a suggestion and the adoption of such a suggestion does not necessarily equate to the claims being free of the cited prior art.

---The invention is a Divisional of U.S. patent application Serial No. 10/371,088 filed on February 21, 2003, now U.S. Patent No. 6,727,235, which itself is a divisional of serial number ~~09/413,449~~ 09/713,449 filed on November 15, 2000, now U.S. Patent No. 6,525,038, which is, in

turn, a Continuation-In-Part of U.S. application serial number 09/446,570 filed on March 27, 2000, now U.S. Patent Number 6,395,720. The invention relates to novel synergistic compositions which selectively control tumor tissue, while healthy tissue is virtually unattacked. The novel compositions are therefore outstandingly suitable for cancer therapy.---

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56-58 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of human bladder tumor using a synergistic combination of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid, fails to reasonably provide enablement for the treatment of cancers sensitive to a synergistic combination of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;

4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

1 and 2) The claimed invention is directed to a synergistic composition comprising 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid (see present claim 54) and a medicament comprising the same further in combination with a pharmaceutically tolerable excipient (see present claim 55). The claimed invention is further drawn to a method for treating cancer sensitive to a synergistic composition of 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid, wherein the composition may also be administered with a pharmaceutically tolerable excipient (see present claims 56-58).

3 and 7) In particular, one skilled in the art could not practice the presently claimed subject matter without undue experimentation because the artisan would not accept on its face that the treatment of all cancers that exhibited some sensitivity to a synergistic composition of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid, in general, could be effectively achieved by the administration of the claimed active agents. Based on the state of the art, as discussed below, the artisan would have only accepted that the treatment of specific types of cancer could be achieved, rather than that such a combination of agents could have been used to treat any known cancer.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support*; assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added).

The present claims circumscribe a method of treating all cancers with sensitivity to a synergistic composition of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by administering the presently claimed active agents, all cancers with any degree of sensitivity whatsoever to such a combination could be treated. However, such a situation is sufficiently unusual that data would need to be shown in order to establish which specific types of cancer have sensitivity to such a composition and how such cancers could be effectively treated through the administration of the claimed active agents. Because the specification fails to direct the skilled artisan as to which cancers are known to be sensitive to such a composition or how one would even go about determining the subset of cancers that would have been reasonably expected to have such a sensitivity, especially in consideration of the highly complex nature of cancer, the specification, which lacks an objective showing of which cancers could be effectively treated using the claimed combination of active agents, is viewed as lacking an enabling disclosure of the same.

It is herein noted that Applicant discloses at page 6, "On account of their pH sensitivity, the compositions according to the invention are only activated in cancer tumors and metastatic areas and therefore represent an ideal cancer therapeutic. It is also to be particularly emphasized that this novel cancer therapeutic acts generally on all tumor types independently of the specific type of cancer." However, such a statement clearly reads on the intent of Applicant to use the presently claimed therapy in the treatment of any known cancer. Once again, in light of the state of the art regarding cancer therapy, which is highly complex and highly unpredictable, the present disclosure fails to provide adequate disclosure directing the skilled artisan to the particular types of cancers that may be effectively treated using the claimed active agents. In fact, Applicant's related disclosure supports the treatment of any cancer type known in the art.

Here, the objective truth that cancer of any type may be treated is doubted because, while the state of the art of cancer treatment is well developed with regard to the *treatment* of *specific* cancer types (see Cecil's Textbook of Medicine at page 1060-1074), the state of the art with regard to *treating or preventing* cancer *in general* is grossly underdeveloped.

In this regard, Cecil's Textbook of Medicine (2000) is cited. In particular, there is no known anticancer agent or combination of anticancer agents that is effective against treating all cancer types, nor is there any known anticancer agent or combination of agents that is effective against inhibiting the growth of any type of cancer cell. The Cecil reference clearly shows that for the various known cancer types, there is not one specific chemotherapeutic agent or combination thereof that is effective at treating cancer or inhibiting the growth of cancer cells for each and every type of cancer (see Table 198-5 at page 1065; Tables 198-6 and 198-7 at page 1066; Table 198-8 at page 1068; and Table 198-9 at page 1071).

Given that there was not known any specific agent or combination of agents effective to treat all known types of cancer, one of ordinary skill in the art would not accept on its face Applicant's statement that such an objective could be achieved in any cancer type. The artisan would have required sufficient direction as to which specific types of cancer could be effectively treated with the presently claimed combination of active agents and, further, how the artisan could predict what particular types of cancer would actually show sensitivity to the presently claimed composition of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid, such that the artisan would have been imbued with at least a reasonable expectation of success in treating the cancer. Such success would not have been reasonably expected for all cancer types given the highly complex and variable nature of all cancers known in the art and that the treatment of all known cancer types would have been an outcome not reasonably expected by one of ordinary skill in the art. To the artisan, the concept of a single agent, or even a combination of agents, that is effective to treat all known types of cancer would have been unique and, thus, met with a great deal of skepticism.

In addition, it is noted that the concept that the combination of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid would have demonstrated synergistic activity in the treatment of any or all known cancer types would also have been extremely unique and, thus, would have been met with a similar degree of skepticism. The artisan would also have required sufficient direction as to which specific types of cancer could be treated with the presently claimed combination of active agents such that the *synergistic* efficacy of the combination would actually be effected. However, the exemplification of synergy in one single type of cancer (i.e., bladder, see Figures 4 and 5) in the absence of any sound scientific

reasoning as to why such results would have been reasonably representative of the same synergistic effect in any known type of cancer is not adequate direction to the skilled artisan as to how the same synergistic effect as presently claimed could be effected in a patient exhibiting a cancer of any known type.

4) Applicant has merely disclosed that by administering the claimed synergistic active agents, one may treat cancer of any type. Based on the discussion in Section 3 above, however, such disclosure clearly is not adequate direction or guidance as to how the proposed agents can be employed to accomplish such objectives in a predictable manner.

5) The specification at pages 17-21 and Figures 4 and 5 provide descriptions and scientific evidence demonstrating that the use of a composition comprising 5-(2,4-difluorophenyl)salicylic acid in combination with 2,4,6-trihydroxybenzoic acid exerts a synergistic effect on inhibiting the proliferation and activity of human bladder tumor cells. Such data, however, is not commensurate in scope with the claimed subject matter. While the present claims encompass the treatment of a cancer of any known type by administering a composition comprising 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid that exerts a synergistic effect, Applicant's data merely establishes that the administration of these compounds has a synergistic effect in the treatment of human bladder tumor cells. However, no data or reasonable scientific basis for extrapolating such results to the larger genus of "cancer" as a whole has been provided that shows the claimed composition is capable of definitively effecting a *synergistic* effect in the treatment of any known type of cancer.

The Examiner acknowledges that the Office does not require the presence of working examples to be present in the disclosure of the invention (see MPEP §2164.02). However, in

light of the state of the art, which recognizes the unpredictable nature of human cancer, there is no apparent disclosure to support the contention that the use of the claim specified active agents could actually effectively treat a cancer of any known type in a *synergistic* manner by simply administering, by any method, an amount of the claimed active agents, since the present specification fails to enable one of ordinary skill in the art to practice the entirety of the presently claimed invention.

6) The burden of enabling the treatment of all types of human cancer is much greater than that of enabling the treatment of a specific, discrete group of cancers known to, or with a reasonable basis for concluding that they would, be responsive to such a treatment. Since the present specification would not enable the skilled artisan to synergistically treat any type of cancer known in the art, a clear burden of undue experimentation would be placed upon the skilled artisan in order to practice the full scope of the presently claimed invention.

8) In view of the discussion of each of the preceding seven factors, the level of skill in this art is high and is at least that of a medical doctor with several years of experience in the art.

Summary

As the cited art and discussion of the above 8 factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that synergistic treatment of cancer of any type could be achieved with the presently claimed combination of agents. In order to actually achieve such an objective, it is clear from the discussion above that the skilled artisan could not rely on Applicant's disclosure as required by 35 U.S.C. § 112, first paragraph. Given that the art fails to recognize, and Applicant

has failed to demonstrate, via direct evidence or sound reasoning, that all types of human cancer could actually be synergistically treated with the presently claimed combination of agents, the skilled artisan would be faced with the impermissible burden of undue experimentation in order to practice this embodiment of the claimed invention. Accordingly, claims 56-58 are deemed properly rejected.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

I Claims 54-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, it is noted that the claims recite the combination of 5-(2,4-difluorophenyl)salicylic acid with "2,4,6-trihydroxybenzoic acid (4,6-dihydroxysalicylic acid)". The recitation of both "2,4,6-trihydroxybenzoic acid" and "4,6-dihydroxysalicylic acid" renders the scope of the claim indefinite because Applicant has failed to make clear how "4,6-dihydroxysalicylic acid" is intended to limit the claim. It appears that both "2,4,6-trihydroxybenzoic acid" and "4,6-dihydroxysalicylic acid" are names that circumscribe the same compound. However, it is unclear whether the parenthetical recitation of "4,6-dihydroxysalicylic acid" is intended to simply make reference to another known name for that same compound, or whether it is intended to limit the claim in another manner. As a result, the claims do not meet

the tenor and express requirements of 35 U.S.C. 112, second paragraph, and, thus, the skilled artisan would not have been reasonably apprised of the scope of the claims.

For these reasons, the claims are properly rejected. For the purposes of examination, the claims will be interpreted to read upon the combination of 5-(2,4-difluorophenyl)salicylic acid and 2,4,6-trihydroxybenzoic acid.

II Claim 57 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

In particular, the claim recites the phrase "wherein said cancer is a carcinomatose disorder" at line 2. Applicant, however, has not defined the word "carcinomatose" in the present disclosure and since it is not a word commonly used in the art, the identity of the subject matter for which Applicant is seeking protection is not clear.

It is noted, though, that should Applicant intend such a word to read on the word "carcinomatous", such that the limitation properly reads "wherein said cancer is a carcinomatous disorder", it would again be unclear how Applicant would intend such a limitation to further limit the independent claim from which it depends (see present claim 56), since the parent claim already recites the treatment of cancer.

For these reasons, the claims fail to meet the tenor and express requirements of 35 U.S.C. 112, second paragraph, and are, thus, properly rejected.

For the purposes of examination, the claim will be interpreted to read upon a "carcinomatous" disorder, i.e., any disorder relating to carcinoma.

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-58 are rejected under 35 U.S.C. 102(b) as being anticipated by Kreutz (WO 98/58639; 1998), citing to corresponding U.S. Patent No. 6,395,720 (2002).

For the purposes of examination, U.S. Patent No. 6,395,720 B1 to Kreutz (Issued May 28, 2002) will be relied upon as the basis for the present rejection. Such a patent is a U.S. National Stage (371) entry of PCT/EP98/02939, of which WO 98/58639 is the International Publication, and is reasonably expected to contain the same subject matter. Such is in accordance with the MPEP at §901.05, which states, "It is possible to cite a foreign language specification as a reference, while at the same time citing an English language version of the specification with a later date as a convenient translation if the latter is in fact a translation." Given that the U.S. Patent to Kreutz was granted its priority claim to the above-cited PCT Application, and also that both documents are members of the same patent family, such is further evidence that U.S. Patent 6,395,720 reads on the same subject matter as that of WO 98/58639. Nevertheless, a translation of WO 98/58639 has been requested for confirmation.

Kreutz teaches a composition comprising at least two benzoic acid derivatives which act synergistically as a mixture with one another (col.2, lines 11-14; see present claim 54-55), including 2,4,6-trihydroxybenzoic acid (col.2, line 25; see present claims 54-55) and 5-(2,4-

difluorophenyl)salicylic acid (col.2, line 27; see present claims 54-55), which has a strong synergistic action for the destruction of tumor tissue (col.2, lines 7-11; see present claim 56), and which may be formulated as a medicament comprising the composition and further comprising a pharmaceutical organic or inorganic excipient (col.6, lines 12-21; see present claim 55), and further wherein the composition may be administered to a patient in need thereof for the treatment of carcinomatous disorders in a pharmaceutically effective amount (col.8, lines 25-29; see present claims 56-58).

Possible Double Patenting Conflict Regarding Copending Applications

Applicant is advised at this time that no statutory or obviousness-type double patenting rejections have been made. However, notice has been taken of copending U.S. Patent Application No. 10/569,630, entitled "Diflunisal for the Treatment of Cancer", which is currently undergoing pre-examination and has not yet been made available to the Examiner for review.

Applicant is advised that should conflicting subject matter be found in such a copending application upon review when it does become available to the Examiner, the appropriate double patenting rejection (i.e., statutory or obviousness-type) will be made in the subsequent Office Action.

Conclusion

Rejection of claims 54-58 is deemed proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

March 14, 2006

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